SENATE BILL 1509
By Stanley

HOUSE BILL 640

By Naifeh

AN ACT to amend Tennessee Code Annotated, Title 53 and Title 68, relative to liability of non-profit healthcare research institutions and their employees, agents, directors, and officers for research activities conducted in connection with efforts to diagnose, treat, or prevent infectious diseases.

WHEREAS, it is hereby recognized by the general assembly that it is in the public's interest to promote and provide for a stable research environment within the State's unique research institution of St. Jude Children's Research Hospital. Such research activities include, but are not limited to, cutting edge research into the development of component parts necessary for use in the production of vaccines that are designed to prevent a variety of infectious diseases; and

WHEREAS, the general assembly recognizes that nonprofit research institutions such as St. Jude, which are not protected by sovereign immunity, and which provide invaluable resources to state public health officials in combating infectious diseases that have a disproportionate impact upon children, have unacceptable liability exposure for the use of component parts and materials resulting from their research activities under current state law; and

WHEREAS, the general assembly recognizes that St. Jude is one of the world's premier biomedical research centers. Funded mostly by charitable donations, St. Jude is the largest cancer research center in the world devoted solely to children, and is the only pediatric research center where the patient's family is never required to pay for treatment not covered by insurance; and

WHEREAS, the general assembly finds that St. Jude engages in valuable vaccine research and surveillance activities, as well as the manufacture and production of novel vaccine and component parts such as seed stocks, cell lines and plasmids; now, therefore,

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, is amended by adding the following language as a new, appropriately designated section:

(a) As used in this section, unless the context otherwise requires:

(1) "Healthcare research institution" means any non-governmental, nonprofit research institution with its principal place of business in this state which is, or which is affiliated with, a hospital or clinic for the treatment of pediatric patients which does not seek payment for treatment provided to patients in the absence of insurance coverage for such treatment. This term includes any or all of the parents, subsidiaries, affiliates, successors and assigns of such institution, and any or all individual trustees, officers, directors, employees, and agents of such institution;

(2) "Countermeasure" means a vaccine or the component parts used in the design, development, clinical testing or investigation or manufacture of a vaccine, including seed stocks, cell lines and plasmids, used to diagnose, mitigate, prevent, treat, cure or otherwise limit the harm of an infectious disease that is:

(i) Approved or cleared under Chapter V of the federal Food, Drug, and Cosmetic Act or licensed under § 351 of the federal Public Health Service Act;

(ii) The object of research for possible use as described in subdivision (2)(i) and is the subject of an exemption under § 505(i) of the federal Food, Drug and Cosmetic Act; or

(iii) Authorized for emergency use in accordance with § 564 of the Federal Food, Drug, and Cosmetic Act; and

(3) "Willful misconduct" means an act or omission that is taken:

(i) Intentionally to achieve a wrongful purpose;

(ii) Knowingly without legal or factual justification; and

(iii) In disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

(b)

(1) A healthcare research institution shall be immune from suit and any liability under state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to, or use by, an individual, including claims from loss caused by, arising out of, relating to, or resulting from the design, development, clinical testing or investigation or manufacture of any countermeasure, unless such loss can be determined to have resulted from the willful misconduct of the healthcare research institution or its employees in accordance with the provisions of subdivision (b)(2).

(2) In any action arising under subdivision (b)(1), the plaintiff shall have the burden of proving, by clear and convincing evidence, willful misconduct by each healthcare research institution, or employee, against which a claim has been asserted and that such willful misconduct caused death or serious physical injury.

SECTION 2. Nothing in this act shall be construed to amend, abrogate or otherwise limit, liability protections currently available to healthcare institutions referenced in this act, and such institutions employees, as otherwise provided by law.

SECTION 3. This act shall take effect July 1, 2007, the public welfare requiring it.